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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 203 and 205

[Docket Nos. 92N-0297 and 88N-0258]

RIN 0905-AC81

**Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992;
Policies, Requirements, and Administrative Procedures; Delay of Effective Date;
Reopening of Administrative Record**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date; reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is delaying until October 1, 2001, the effective date and reopening the administrative record to receive additional comments regarding certain requirements of a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). The other provisions of the final rule become effective on December 4, 2000. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA) and the FDA Modernization Act of 1997 (the Modernization Act). FDA is delaying the effective date for certain requirements relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record. FDA is also delaying the effective date of another requirement that would prohibit blood centers functioning as "health care entities" to act as wholesale distributors of blood derivatives. The agency is taking this action to address numerous concerns about the provisions raised by affected parties.

NEC 2

DATES: The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until October 1, 2001. The administrative record is reopened until [*insert date 60 days after date of publication in the Federal Register*], to receive additional comments on these provisions.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Lee D. Korb, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA as modified by the PDA amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs.

Section 503(e)(1)(A) of the act states that each person who is engaged in the wholesale distribution of a prescription drug who is not the manufacturer or an authorized distributor of record for the drug must, before each wholesale distribution of a drug, provide to the person receiving the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction. Section 503(e)(4)(A) of the act states that, for the purposes of section 503(e), the term “authorized distributors of record”

means those distributors with whom a manufacturer has established an “ongoing relationship” to distribute the manufacturer’s products.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing these and other provisions of PDMA (64 FR 67720). Section 203.50 requires that, before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller must provide to the purchaser a statement identifying each prior sale, purchase, or trade of the drug. The identifying statement must include the proprietary and established name of the drug, its dosage, the container size, the number of containers, lot or control numbers of the drug being distributed, the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer, and the date of each previous transaction. Section 203.3(b) defines “authorized distributor of record” as a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer’s products. “Ongoing relationship” is defined in 203.3(u) to mean an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer’s products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer’s entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

Thus, the final rule requires unauthorized distributors (i.e., those distributors who do not have a written authorization agreement) to provide a drug origin statement to purchasers showing the entire prior sales history of the drug back to the first sale by the manufacturer. As discussed in the preamble to the final rule (64 FR 67720 at 67747), manufacturers and authorized distributors of record are not required to provide an identifying statement when selling a drug, although the

agency encouraged them to do so voluntarily to permit unauthorized distributors to continue to be able to purchase products from them.¹

The provisions in the final rule related to wholesale distribution of prescription drugs by unauthorized distributors (i.e., §§ 203.3(u) and 203.50) were adopted from the provisions in the proposed rule published in the **Federal Register** of March 14, 1994 (59 FR 11842), and are essentially the same as the proposed provisions, except the definition for “ongoing relationship” in the proposed rule was revised to eliminate certain requirements.² The agency received two comments on the proposed definition of ongoing relationship and one comment on proposed § 203.50, and responded in detail to those comments in the preamble to the final rule (see 64 FR 67720 at 67727, 67728, and 67747).

Section 503(c)(3)(A) of the act states that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any drug that was purchased by a public or private hospital or other health care entity. Section 503(c)(3)(B) states several exceptions to section 503(c)(3)(A), none of which are relevant to this discussion. Section 503(c)(3) also states that “[f]or purposes of this paragraph, the term ‘entity’ does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.”

In the final rule of December 3, 1999, § 203.20 provides, with certain exceptions, that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was purchased by a public or private hospital or other health care entity or donated or supplied

¹ An unauthorized wholesale distributor that purchases a product from a manufacturer or authorized distributor of record without an identifying statement showing the prior sales of the drug could not provide an identifying statement to its purchasers and, therefore, could not conduct further wholesale transactions of the drug in compliance with § 203.50.

² The proposed rule defined “ongoing relationship” to require a written agreement and, in addition, the following two requirements that were eliminated in the final rule: (1) That a sale be completed under the written agreement and (2) that the distributor be listed on the manufacturer’s list of authorized distributors.

at a reduced price to a charitable organization. In § 203.3(q) of the final rule, “Health care entity” is defined as meaning any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or wholesale distributor. Under both the act and the final rule, a person could not simultaneously be a health care entity and a retail pharmacy or wholesale distributor. Thus, under the final rule, blood centers functioning as health care entities could not engage in wholesale distribution of prescription drugs, except for blood and blood components intended for transfusion, which are exempt from the PDMA under § 203.1 of the final rule. Blood and blood components include whole blood, red blood cells, platelets and cryoprecipitated antihemophilic factor which are prepared by blood banks who collect blood from donors and separate out the components using physical or mechanical means. Blood derivatives are derived from human blood, plasma, or serum through a chemical fractionation manufacturing process. Examples of blood derivative products include albumin, antihemophilic factor, immune globulin, and alpha-1 anti-trypsin. As discussed in the preamble to the final rule in response to comments (64 FR 67720 at 67725, 67726, and 67727), blood derivative products are not blood or blood components intended for transfusion and therefore could not be distributed by health care entities, including full service blood centers that function as health care entities, after the final rule goes into effect.

II. Description and Rationale for a Partial Delay of the Effective Date of the Final Rule

A. Wholesale Distribution by Unauthorized Distributors

Since publication of the final rule, the agency has received letters and petitions and has had other communications with industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. In early February 2000, the agency met with representatives from the wholesale industry and industry associations. The meeting participants discussed their concerns with both: (1) The requirement in § 203.3(u) that there be a written authorization agreement between a manufacturer and distributor for the distributor to be considered

an authorized distributor of record under § 203.3(b), and (2) the requirement in § 203.50 that unauthorized distributors provide an identifying statement showing all prior sales going back to the manufacturer.

The meeting participants asserted that manufacturers are unwilling to enter into written authorization agreements with the majority of smaller wholesalers so that these wholesalers cannot become authorized distributors of record for the drugs they sell and, hence, must provide an identifying statement for these drugs. The meeting participants also said that smaller wholesalers cannot obtain an identifying statement showing all prior sales of the drugs they purchase for sale because a large portion of these drugs are purchased from authorized distributors who are not required to provide identifying statements and are unwilling to voluntarily provide them. The meeting participants asserted that authorized distributors will not voluntarily provide identifying statements when they sell drugs to unauthorized distributors because it would require them to change their warehouse and business procedures, which would entail additional effort and expense.

The meeting participants asserted that implementation of the final rule will prevent over 4,000 smaller, unauthorized distributors from distributing drugs to their customers and may put them out of business, at least with respect to their prescription drug wholesale business. They also asserted that because many of their customers are smaller retail outlets that are not served by larger distributors, implementation of the final rule may leave certain markets for prescription drugs, and ultimately consumers for prescription drugs, underserved.

In addition to the meeting discussed above and other informal communications that FDA has had with industry, industry associations, and Congress, FDA received a petition for stay of action requesting that the relevant provisions of the final rule be stayed until October 1, 2001. The agency also received a petition for reconsideration from the Small Business Administration (SBA) requesting that FDA reconsider the final rule and suspend its effective date based on the projected severe economic impact it would have on over 4,000 small businesses. The petitions argued that the requirement for a written agreement in § 203.3(u) is unreasonable because manufacturers are

not willing to enter such agreements with the majority of smaller distributors. The petitions also asserted that authorized wholesalers are not now able and could not provide, at a reasonable cost, an identifying statement to their unauthorized distributor customers that meets the requirements of § 203.50 of the final rule. The SBA petition asserted that, if the effective date of the final rule is not stayed, drug products now in the inventory of wholesalers will have to be cleared and new orders will have to cease or be severely limited in order to comply with the final rule's December 4, 2000 effective date, with corresponding disruptions in the distribution of drugs possible by summer, 2000.

B. Distribution of Blood Derivatives by Health Care Entities

Since the time of the proposed rule, FDA has received 2 letters, one from a large blood center and the other from an association representing the blood center industry, and has held several meetings to discuss the implications of the regulations on blood centers that distribute blood derivative products and provide health care as a service to the hospitals and patients they serve. The blood center industry asserts that the regulations and, particularly the definition of "health care entity," will severely inhibit their ability to provide full service care to the detriment of client hospitals and the patients they serve, and may disrupt the distribution of these products to the public. The agency has also received a letter from a member of Congress on this issue. Although the agency was aware of this issue at the time the final rule was published, we believed that application of § 203.3(q) to blood centers would not result in a disruption in the distribution of blood derivative products. However, comments and information provided by representatives of the blood center industry have persuaded us that the final rule could disrupt the availability of blood derivative products to the public.

C. Partial Delay of the Effective Date

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency has

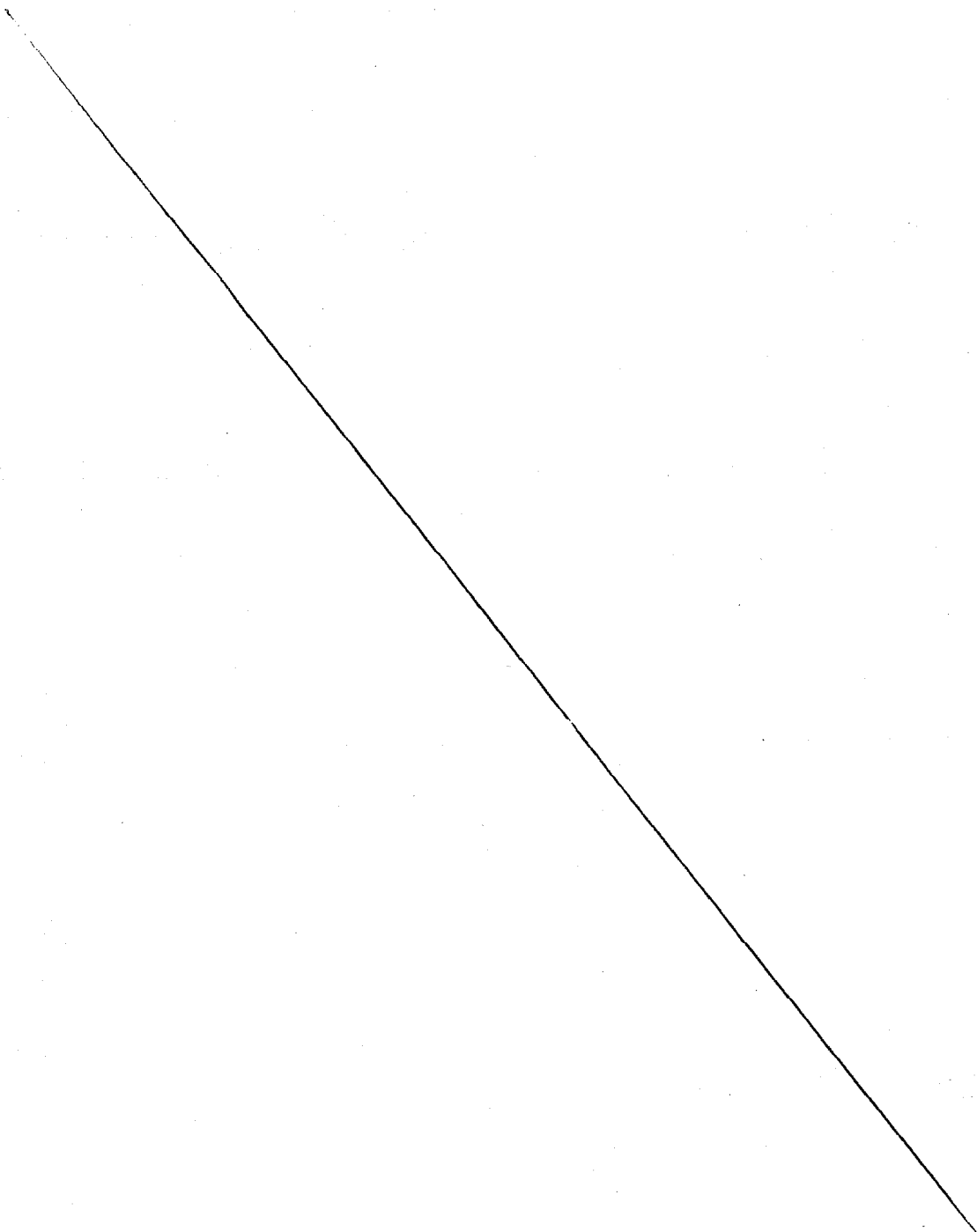
decided to delay the effective date for those sections of the final rule until October 1, 2001. Additionally, the agency has decided to delay the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, until October 1, 2001. All other provisions of the rule will become effective on December 4, 2000. This action should not be construed to indicate that FDA necessarily agrees with or has made decisions about the substantive arguments made in the petitions and other submissions related to implementation of §§ 203.3(u) and 203.50 or § 203.3(q), as it applies to wholesale distribution of blood derivatives by health care entities.

III. Reopening of the Administrative Record

The agency believes that providing additional time before these are to become effective is appropriate to permit the agency to obtain more information about the possible consequences of implementing these provisions, to further evaluate the issues involved, and to seek a legislative resolution to these issues, if necessary. Therefore, the agency is reopening the administrative record to receive additional comments on these provisions from interested individuals. Regarding §§ 203.3(u) and 203.50, the agency is especially interested in gaining further insight into the potential impact of the provisions on the wholesale distribution system generally, and on the ability of smaller pharmacies and other prescription drug retailers to obtain prescription drugs. In addition, the agency is seeking comments on the potential economic impact of the provisions on smaller wholesale distributors that are not authorized distributors of record. Regarding § 203.3(q), the agency also invites comment on the economic and public health impact of including full service blood centers under the definition of "health care entity," thereby prohibiting the wholesale distribution of blood derived products by such entities.

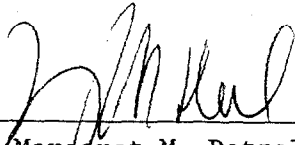
Interested persons may submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments regarding this proposal by *[insert date 60 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this delay of the effective date is in the public interest.

Dated: 4/26/00
April 26, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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